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Subject: Environmental Defense comments on Ethyl Monochloroacetate (EMCA)

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(Submitted via Internet 12/23/02 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and cldeford@dow.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Ethyl Monochloroacetate (CAS# 105-39-5), as submitted by the Dow Chemical Company.

The robust summary/test plan for ethyl monochloroacetate (EMCA) was posted on the EPA Chemical Right to Know web site on January 24, 2002, with public comments thereon due on May 24, 2002. Environmental Defense prepared comments on this test plan for timely submission, but discovered in December 2002 we had inadvertently failed to submit them. On December 18, 2002, EPA posted Dow's November 15 response to EPA's August 22 comments on Dow's original robust summary/test plan. We have revised our comments in light of that response.

Our comments at this time focus on two points: (i) the assertion that EMCA qualifies as a closed-system intermediate, and (ii) other comments.

A. Closed-system-intermediate status. Two issues arise in this context. First is whether EMCA as manufactured by Dow qualifies as a closed system intermediate. Dow's initial submission provided some information on the manner in which EMCA is produced, stored and used by Dow. EPA's comments pointed out that additional supporting detail is needed, including a process description or flow diagram, and information on wastes generated following manufacture, the chemical's presence in downstream products, and information on processing and transfer by customers; we concur.

In addition, Dow's initial submission notes that there is an EMCA importer, but does not provide any information relating to whether use of imported EMCA occurs on a closed-system basis. Some of the major uses of EMCA identified by EPA in its comments (e.g., military poison, vat dyestuffs) lead us to question whether the claim of closed system intermediate status can be justified; unless Dow is able to provide information demonstrating conclusively that such uses of EMCA do not in fact occur, any assumption of closed system intermediate is unwarranted.

In its November 15 response to EPA's comments, Dow states that it "appreciates [EPA's] interest in seeking adequate information to confirm that EMCA is used as a closed-system intermediate. However, Dow is unsure that it can provide further detail without claiming it as Confidential Business Information (CBI)." Dow asked to schedule a conference call with EPA to discuss the issue further. It is not clear whether the additional information that Dow might provide relates only to its own operations, or to those of the other manufacturer and the importer as well.

In any event, we are extremely disturbed at the suggestion that non-public information allegedly supporting a closed-system-intermediate designation could provide a basis for negating otherwise-applicable data requirements. This approach is not in keeping with the overall purpose of the HPV program as a chemical right-to-know initiative. At the very least, Dow should make public and subject to review an up-front rationale for and substantiation of the need for confidentiality.

Second, it should be noted that ALL producers (including both manufacturers and importers) must qualify for closed-system status in order for a chemical to be designated as a closed-system intermediate. Thus, even if Dow can provide appropriate documentation that Dow-produced EMCA qualifies as closed-system, EMCA cannot be designated as closed-system absent documentation that the practices of the importer likewise qualify as closed-system.

B. Other comments.

1. The chemical structure of EMCA should be included in the Description Section.

2. EMCA is an ester. Thus, it is anticipated that EMCA will be readily hydrolyzed by a variety of biological systems including mammals. The primary product of concern resulting from EMCA hydrolysis would be monochloroacetic acid. Monochloroacetic acid has been the subject of considerable study by the National Toxicology Program and others. This fact and relevant data should be discussed in the Test Plan and these studies should be referenced as part of the Robust Summaries for EMCA.

3. EMCA has apparently been the subject of numerous studies to characterize its toxicity. However, in many cases the Robust Summaries' discussion of these studies are incomplete. Critical data such as number of animals tested, exposure time and even dose are not given. If these data are available they should be provided. If they are not, these studies should not be considered reliable.

4. The Test Plan for EMCA lists data for repeated dose studies and, in parentheses, refers to carcinogenicity studies. The Robust Summary does not list data for repeat dose studies, but cites the carcinogenicity studies at a latter point. It is likely that repeated dose studies were conducted as part of the carcinogenicity studies. If so, results of those studies should be described and referenced. On page 7 of the Test Plan results of repeated dose studies are described as negative, but that statement refers to the carcinogenicity study results. As stated previously, we assume that, in the course of dose setting for the carcinogenicity studies, repeated dose studies were conducted at doses that resulted in adverse effects. Those adverse health effects should be described in the Test Plan.

5. A number of the Robust Summaries of the carcinogenicity studies are not in English. Where possible, those results should be translated.

6. A number of the robust summaries of the carcinogenicity studies (repeated dose studies) do not list study results. We assume that some conclusion was reached for such an extensive study. If no conclusion was reached then the study must have been considered inadequate or the results judged inconclusive. In either case some result should be listed.

7. Unless EMCA is shown to qualify as a closed-system intermediate, the adequacy of existing reproductive and subchronic toxicity data should also be evaluated (such data may be available or extrapolatable through the

other studies). If such data are not found to be adequate, new tests need to be conducted for these endpoints.

Thank you for this opportunity to comment.

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